K071640

510(k) Summary

JUL 12 2007

Submitted By:

Theodore Heise, Ph.D., RAC
Vice President Regulatory Scientific Affairs
Cook Incorporated
750 Daniels Way (PO Box 489)
Bloomington, IN 47404 (47402)
812-339-2235
June 14, 2007

Device:

Trade Name:	Cook Incorporated Spectrum® VentriClear™ II Ventricular Drainage Catheter Set
Proposed Classification:	Catheter, Ventricular (Containing Antibiotic or Antimicrobial Agents) NHC (21 CFR §882.4100)

Indications for Use

The Spectrum® VentriClear™ II Ventricular Drainage Catheter Set is intended for obtaining access to a ventricular cavity of the brain for short-term use to externally drain fluid for the purpose of relieving elevated intracranial pressure or fluid volume. The device is supplied sterile and is intended for one-time use.

Predicate Devices:

Spectrum® VentriClear™ II Ventricular Drainage Catheter Set is similar in terms of intended use, principles of operation, materials of construction and technological characteristics to the predicate Cook Spectrum® Ventricular Drainage Catheter Set.

Device Description:

Spectrum® VentriClear™ II Ventricular Drainage Catheter Set includes a silicone 2.8 mm (9 Fr.) ventricular catheter available in a 33 cm length with numbered markings and 16 sideports. VentriClear™ II is impregnated with minocycline and rifampin. This device is supplied sterile and is intended for one-time use.

Substantial Equivalence:

The Spectrum® VentriClear™ II Ventricular Drainage Catheter Set is similar to the Cook Incorporated Spectrum® Ventricular Drainage Catheter Set (D.C. # K011812). The similar indications for use, principles of operation, technological characteristics, and performance testing results of VentriClear™ II as compared to the predicate device support a determination of substantial equivalence.

Test Data:

Spectrum® VentriClear™ II Ventricular Drainage Catheter Set was subjected to the following tests to assure reliable design and performance under the specified testing parameters.

1. HPLC testing
2. Tensile testing
3. Liquid leakage testing
4. Burst pressure testing
5. Biocompatibility
6. Gravity flow rate testing

The results of these tests provide reasonable assurance that the device conforms to the requirements necessary for its use as a ventricular catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2007

Cooke Incorporated
% Theodore Heise, Ph.D., RAC
VP, Regulatory Scientific Affairs
750 Daniels Way
Bloomington, Indiana 47404

Re: K071640
Trade/Device Name: Spectrum® VentriClear™ II Ventricular Drainage Catheter Set
Regulation Number: 21 CFR 882.4100
Regulation Name: Ventricular catheter
Regulatory Class: II
Product Code: NHC
Dated: June 14, 2007
Received: June 15, 2007

Dear Dr. Heise:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

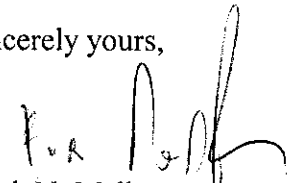
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071640

Device Name: Spectrum® VentriClear™ II Ventricular Drainage Catheter Set.

Indications for Use: Intended for obtaining access to a ventricular cavity of the brain for short-term use to externally drain fluid for the purpose of relieving elevated intracranial pressure or fluid volume.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071640

Prescription Use XX (Per 21 CFR 801.109) OR Over–the-Counter Use____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)